#14

PATENT
Attorney Docket No. 00537/149003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: **M. Culler et al.**	EXAMINER: **TELLER, ROY** ART UNIT: **1653**
APPLICATION NO.: **09/761,605**	
FILED: **JANUARY 16, 2001**	
FOR: **METHOD OF INHIBITING FIBROSIS WITH A SOMATOSTATIN AGONIST**	

I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Assistant Commissioner of Patents, Washington, D.C. 20231.
Date of Deposit 26-Feb-03
Brian R. Morrill

Hon. Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

REPLY UNDER 37 C.F.R. §1.111

This is in reply to the Office Action mailed August 26, 2002, in respect of the above-captioned patent application, (hereinafter "instant application), the period for response thereto having been extended to expire on February 26, 2003, pursuant to a Petition for Extension of Time, filed herewith.

REMARKS

Reconsideration of the Office Action mailed August 26, 2002, (hereinafter "instant Office Action"), and withdrawal of the rejection of claims 142 and 143 are respectfully requested.

In the instant Office Action, claims 142-143 are listed as pending and claims 142-143 are listed as rejected.

Claim Rejections - 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 142 and 143 under 35 U.S.C. §112, first paragraph, for the reasons stated at pages 2 - 4 of

the Instant Office Action. Applicants respectfully traverse this rejection.

As an initial matter Applicants note that this rejection actually consists of two parts: a first part comprising an objection under 35 U.S.C. 132 concerning the amendments offered by Applicants in Applicants' reply dated February 14, 2002; and a second part comprising a rejection under 35 U.S.C. 112, first paragraph, concerning the affect of said amendments on the content of the claims. These two parts will be addressed in turn.

A. Objection to Amendments under 35 U.S.C. 132

For ease of reference the objection to the amendments is put forth below in its entirety, except were noted:

> The amendment filed 2/14/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:
>
> The amended material in claims 142 and 143 are not supported by the instant specification. Claim 142 states "...said fibrosis is not in the kidney, in the lung, in the liver, in the skin, of the central nervous system, in bone or bone marrow, in the cardiovascular system, in an endocrine organ, or in the gastro-intestinal system, and further provided that said fibrosis is not periportal fibrosis" The instant specification recites "... preferably the fibrosis is in the kidney, lung, liver, skin, central nervous system, bone or bone marrow, cardiovascular system, in an endocrine organ, or gastro-intestinal system." [Citations to specification deleted.]
>
> Claims 142 and 143 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The reasons have been set forth in the above objection.

> Applicant is required to cancel the new matter in the reply to this Office Action.

It is not immediately clear whether additional text was intended to be included by the Examiner, e.g., after the first paragraph of the above-quoted text. Applicants understanding of the objection taken as a whole is that the proviso amended to claim 142, "provided said fibrosis is not in the kidney, in the lung, ... and further provided that said fibrosis is not periportal fibrosis", allegedly introduces new matter into the claim. Applicants respectfully request clarification of the objection should Applicants' understanding be incorrect.

Applicants respectfully submit that the foregoing proviso does not introduce new matter. Rather said proviso merely excludes from claim 142 subject matter which either (1) has been allowed in the immediate "parent" application (USSN 09/254,097, issued as US Patent No. 6,268,342), of the instant application, or (2) which might be alleged to be disclosed in the Tracy, et al., reference of record. (See Applicants' February 14, 2002, Reply.) In other words, *all* of the subject matter covered by claim 142, as presently amended, is disclosed in the instant application. For example, the specification discloses at page 2, lines 25-31, that:

> In one aspect, this invention provides a method of inhibiting fibrosis in a patient, said method comprising administering a therapeutically effective amount of somatostatin or a somatostatin agonist to said patient; a method which is preferred of the foregoing method is wherein said method comprises administering a therapeutically effective amount of a somatostatin agonist to said patient.

Similarly, the specification discloses various additional aspects of the invention providing a method of inhibiting fibrosis in a patient, wherein no limitation on the location of the fibrosis within the body is recited. See, e.g.:

page 5, lines 15-31, particularly lines 15-18;

page 5, line 32 - page 6, line 33, particularly page 5, line 32 - page 6, line 1;

page 6, line 34 - page 7, line 9, particularly page 6, line 34 - page 7, line 1;

page 7, line 10 - page 10, line 27, particularly page 7, lines 10 - 13;

page 10, line 28 - page 11, line 5, particularly page 10, lines 28 - 31;

page 17, lines 5 - 14;

page 17, lines 15 - 23;

page 18, lines 7 - 11;

page 18, lines 17 - 25; and

page 22, lines 8 - 9.

Note that all of the immediately foregoing passages disclose treatment of fibrosis in the body generally; i.e., without limitation as to location. The passage at page 22, lines 8 - 9, is particularly clear on this point, disclosing that:

> The fibrosis which is inhibited can be located *in various parts of the body* and can be of a particular kind, *for example*, the fibrosis may be located:

(emphasis added).

It is clear from the foregoing passages that (1) the various specific sites of fibrosis discussed in the specification are merely exemplary, and (2) that the specification discloses not only the treatment of fibrosis that occurs in the exemplary tissues, e.g., the kidney, the lung, the liver, etc., (i.e., in the tissues delineated in the proviso), but also the treatment of fibrosis that occurs tissues *not* explicitly exemplified; i.e., *not* the kidney, the lung, the liver, etc.

Thus, the full breadth of the subject matter of claim 142, as presently amended, is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had

possession of the claimed invention. Accordingly the objection under 35 U.S.C. 132 is obviated. Applicants respectfully request that the objection be withdrawn.

B. Rejection under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 142 and 143 for the reasons provided at page 3, bottom, through page 4, top, of the instant Office Action. Specifically, the Examiner alleges that:

> The negative limitations in claim 142 would appear to prevent the operation of the invention *in vivo*, thus, the claim is indefinite as to being carried out in a patient. With the negative limitations claim 142 states where the fibrosis is not: not in the kidney, in the lung, etc. The claim should specify where the fibrosis is.
>
> Claim 142 and 143 should set forth an effective amount to be used in the methods of administering a therapeutically effective amount of the somatostatin or somatostatin agonist to the patient. The claims should state what the endpoint or conditions (time, dose, etc.) of the treatment are supposed to be.

Regarding the first paragraph of the immediately foregoing rejection, Applicants respectfully suggest that the limitation in claim 142 that the fibrosis occur "in a patient" sufficiently identifies the location of the fibrosis as to enable a skilled artisan to practice the invention. Further, as noted above the specification contains a number of passages disclosing that the method of treatment may be practiced in respect of fibrosis in the body without limitation to any specific tissue type. Significantly, the Examiner has neither indicated how "[t]he negative limitations ... prevent the operation of the invention *in vivo*", nor cited any authority for the proposition that claims to a method of treatment of a physiologically diffuse disorder, such as fibrosis, must be limited to specifically enumerated tissue types.

Regarding the second paragraph of the immediately foregoing rejection, Applicants respectfully suggest that requiring

Applicants to insert limitations into the claims in respect of specific dosing regimens amounts to a requirement that Applicants perform human clinical trials as a condition of patentability. The Examiner has cited no authority in support of such a requirement and Applicants respectfully suggest that no such authority exists. On the contrary, Applicants respectfully suggest that the derivation of specific dosage forms and regimens is well within the skill of those practicing in the pharmaceutical arts. Indeed performance of studies related thereto comprises a routine component of the drug development process.

To be sure Applicants have made disclosures in the specification in respect of dosages generally (see page 18, lines 26-34) as well as a preferred dosage range (see page 19, lines 1 - 3). Applicants provide further extensive disclosures in the specification in respect of drug formulation and routes of administration (see page 19, line 4 through page 20, line 32). Still, in the absence of compelling legal authority to the contrary Applicants should not now be required to limit the claims to any specific dosage amount, formulation or regimen.

Accordingly, the rejection of claims 142 and 143 under 35 U.S.C. 112, first paragraph, is obviated. Applicants respectfully request that the rejection be withdrawn.

Claim Rejections - Double Patenting

The Examiner has rejected claims 142 and 143 under the judicially created doctrine of obviousness-type double patenting over claims 1 and 2 of U.S. Patent No. 6,268,342. The Examiner reasons that the claims are not patentably distinct because:

> claim 142 detail[s] where the fibrosis is not, but claim 1 of the '342 patent include[s] all locations of fibrosis. This includes where the fibrosis is not currently recited in the amended claim 142. Claim 143

recites administering a somatostatin agonist as does claim 2 of the '342 patent.

Applicants respectfully traverse this rejection.

The text of claim 1 of the '342 patent is as follows:

> 1. A method of inhibiting fibrosis in a patient said method comprising administering a therapeutically effective amount of somatostatin or a somatostatin agonist to said patient, *wherein said fibrosis is in the kidney, in the lung, in the liver, in the skin, of the central nervous system, in bone or bone marrow, in the cardiovascular system, in an endocrine organ or in the gastro-intestinal system*.

(emphasis added).

As can be readily appreciated, claim 1 of the '342 is not on its face drawn to the treatment of fibrosis that occurs in "all locations" of the body. Rather by its terms claim 1 of the '342 is drawn to the treatment of fibrosis in the kidney, lung, liver, skin, the central nervous system, an endocrine organ or the gastro-intestinal system, (and equivalents of each). Indeed it is the object of claim 142 as presently amended explicitly to provide for the treatment of fibrosis that occurs in tissues of the body that are not among those listed (or their equivalents) in claim 1 of the '342 patent.

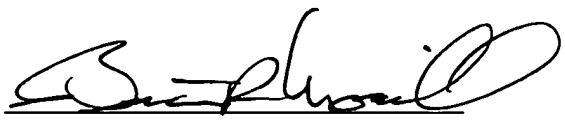
Accordingly, the rejection of claims 142 and 143 under the judicially created doctrine of obviousness-type double patenting is obviated. Applicants respectfully request that the rejection be withdrawn.

Conclusion

Based upon the foregoing, Applicants respectfully submit that claims 142 and 143, as presently amended, are in condition for allowance. Prompt and favorable action is earnestly solicited.

Respectfully submitted,

Date: 26.Feb.03



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